

General

Guideline Title

The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia.

Bibliographic Source(s)

Neunert C, Lim W, Crowther M, Cohen A, Solberg L Jr, Crowther MA, American Society of Hematology. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. Blood. 2011 Apr 21;117(16):4190-207. [162 references] PubMed

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Levels of evidence (1-2) and grades of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

Summary of Recommendations

Section 1: Immune Thrombocytopenia (ITP) in Children

Case 1: Newly Diagnosed ITP in Children

Diagnosis of ITP

1.1.A. The guideline panel recommends:

- Bone marrow examination is unnecessary in children and adolescents with the typical features of ITP (Grade 1B).
- Bone marrow examination is not necessary in children who fail intravenous immunoglobulin (IVIg) therapy (Grade 1B).

1.1.B. The guideline panel suggests:

- Bone marrow examination is also not necessary in similar patients prior to initiation of treatment with corticosteroids or before splenectomy (Grade 2C).
- Testing for antinuclear antibodies is not necessary in the evaluation of children and adolescents with suspected ITP (Grade 2C)

Initial Management of ITP

1.2.A. The guideline panel recommends:

 Children with no bleeding or mild bleeding (defined as skin manifestations only, such as bruising and petechiae) be managed with observation alone regardless of platelet count (Grade 1B).

Initial Pharmacologic Management of Pediatric ITP

1.3.A. The guideline panel recommends:

- For pediatric patients requiring treatment, a single dose of IVIg (0.8-1 g/kg) or a short course of corticosteroids be used as first-line treatment (Grade 1B).
- IVIg can be used if a more rapid increase in the platelet count is desired (Grade 1B).
- Anti-D immunoglobulin (anti-D) therapy is not advised in children with a hemoglobin concentration that is decreased due to bleeding, or with evidence of autoimmune hemolysis (Grade 1C).

1.3.B. The guideline panel suggests:

• A single dose of anti-D can be used as first-line treatment in Rhesus (Rh)-positive, nonsplenectomized children requiring treatment (Grade 2B).

Case 2: Children Who Are Treatment Nonresponders

Appropriate Second-line Treatments for Pediatric ITP

2.1.A. The guideline panel suggests:

- Rituximab be considered for children or adolescents with ITP who have significant ongoing bleeding despite treatment with IVIg, anti-D, or conventional doses of corticosteroids (Grade 2C).
- Rituximab may also be considered as an alternative to splenectomy in children and adolescents with chronic ITP or in patients who do not respond favorably to splenectomy (Grade 2C).
- High-dose dexamethasone may be considered for children or adolescents with ITP who have significant ongoing bleeding despite treatment
 with IVIg, anti-D, or conventional doses of corticosteroids (Grade 2C).
- High-dose dexamethasone may also be considered as an alternative to splenectomy in children and adolescents with chronic ITP or in
 patients who do not respond favorably to splenectomy (Grade 2C).

Splenectomy for Persistent or Chronic ITP or ITP Unresponsive to Initial Measures

2.2.A. The guideline panel recommends:

Splenectomy for children and adolescents with chronic or persistent ITP who have significant or persistent bleeding, and lack of
responsiveness or intolerance of other therapies such as corticosteroids, IVIg, and anti-D, and/or who have a need for improved quality of
life (Grade 1B).

2.2.B. The guideline panel suggests:

Splenectomy or other interventions with potentially serious complications be delayed for at least 12 months, unless accompanied by severe
disease defined by the International Working Group as unresponsive to other measures or other quality of life considerations (Grade 2C).

Helicobacter pylori Testing in Children with Persistent or Chronic ITP

2.3.A. The guideline panel recommends:

• Against routine testing for *H pylori* in children with chronic ITP (Grade 1B).

Case 3: Management of Measles-Mumps-Rubella (MMR)-associated ITP

3.1.A. The guideline panel recommends:

- Children with a history of ITP who are unimmunized receive their scheduled first MMR vaccine (Grade 1B).
- In children with either nonvaccine or vaccine-related ITP who have already received their first dose of MMR vaccine, vaccine titers can be checked. If the child displays full immunity (90%-95% of children), then no further MMR vaccine should be given. If the child does not have

adequate immunity, then the child should be re-immunized with MMR vaccine at the recommended age (Grade 1B).

Section 2: ITP in the Adult

Case 4: Newly Diagnosed ITP in the Adult

Initial Diagnosis of ITP

4.1.A. The guideline panel recommends:

• Testing patients for hepatitis C virus (HCV) and human immunodeficiency virus (HIV) (Grade 1B).

4.1.B. The guideline panel suggests:

- Further investigations if there are abnormalities (other than thrombocytopenia and perhaps findings of iron deficiency) in the blood count or smear (Grade 2C).
- A bone marrow examination is not necessary irrespective of age in patients presenting with typical ITP (Grade 2C).

Treatment of Newly Diagnosed Adult ITP

4.2.A. The guideline panel suggests:

• Treatment be administered for newly diagnosed patients with a platelet count <30 X 10⁹/L (Grade 2C).

First-line Treatment of Adult ITP

4.3.A. The guideline panel suggests:

- Longer courses of corticosteroids are preferred over shorter courses of corticosteroids or IVIg as first-line treatment (Grade 2B).
- IVIg be used with corticosteroids when a more rapid increase in platelet count is required (Grade 2B).
- Either IVIg or anti-D (in appropriate patients) be used as a first-line treatment if corticosteroids are contraindicated (Grade 2C).
- If IVIg is used, the dose should initially be 1 g/kg as a one-time dose. This dosage may be repeated if necessary (Grade 2B).

Treatment of Patients Who Are Unresponsive to or Relapse after Initial Corticosteroid Therapy

4.4.A. The guideline panel recommends:

- Splenectomy for patients who have failed corticosteroid therapy (Grade 1B).
- Thrombopoietin receptor agonists for patients at risk of bleeding who relapse after splenectomy or who have a contraindication to splenectomy and who have failed at least one other therapy (Grade 1B).

4.4.B. The guideline panel suggests:

- Thrombopoietin receptor agonists may be considered for patients at risk of bleeding who have failed one line of therapy such as corticosteroids or IVIg and who have not had splenectomy (Grade 2C).
- Rituximab may be considered for patients at risk of bleeding who have failed one line of therapy such as corticosteroids, IVIg, or splenectomy (Grade 2C).

Laparoscopic versus Open Splenectomy and Vaccination Prior to Splenectomy

4.5.A. The guideline panel recommends:

That for medically suitable patients, both laparoscopic and open splenectomy offer similar efficacy (Grade 1C).

Case 5: Treatment of Adult ITP after Splenectomy

Treatment of ITP after Splenectomy

5.1.A. The guideline panel recommends:

• Against further treatment in asymptomatic patients after splenectomy who have platelet counts >30 X 10⁹/L (Grade 1C).

Case 6: Treatment of ITP in Pregnancy

Management of ITP during Pregnancy

6.1.A. The guideline panel recommends:

• Pregnant patients requiring treatment receive either corticosteroids or IVIg (Grade 1C).

Treatment of ITP during Labor and Delivery

6.2.A. The guideline panel suggests:

For pregnant women with ITP, the mode of delivery should be based on obstetric indications (Grade 2C).

Case 7: Treatment of Specific Forms of Secondary ITP

Management of Secondary ITP, HCV-associated

7.1.A. The guideline panel suggests:

- In patients with secondary ITP due to HCV infection, antiviral therapy should be considered in the absence of contraindications (Grade
 2C). However, the platelet count should be closely monitored due to a risk of worsening thrombocytopenia attributable to interferon.
- If treatment for ITP is required, the initial treatment should be IVIg (Grade 2C).

Management of Secondary ITP, HIV-associated

7.2.A. The guideline panel recommends:

- For patients with secondary ITP due to HIV, treatment of the HIV infection with antiviral therapy should be considered before other treatment options unless the patient has clinical significant bleeding complications (Grade 1A).
- If treatment for ITP is required, initial treatment should consist of corticosteroids, IVIg, or anti-D (Grade 2C) and splenectomy in preference to other agents in symptomatic patients who fail corticosteroids, IVIg, or anti-D (Grade 2C).

Management of Secondary ITP, Hpylori-associated

7.3.A. The guideline panel recommends:

• That eradication therapy be administered in patients who are found to have *Hpylori* infection (based on urea breath tests, stool antigen tests, or endoscopic biopsies) (Grade 1B).

7.3.B. The guideline panel suggests:

• Screening for *H pylori* be considered in patients with ITP in whom eradication therapy would be used if testing is positive (Grade 2C).

Definitions:

GRADING the Evidence

The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system provides a score for a recommendation of 1A, 1B, 1C, 2A, 2B, or 2C.

The numeric value indicates the strength of the recommendation:

A value of 1 indicates a high degree of confidence that the desirable outcomes of an intervention exceed the undesirable effects (or vice versa) in most patient populations. In general, a strong recommendation requires excellent-quality data from a variety of clinical situations. However, in some settings a strong recommendation may be derived from lesser-quality evidence if the intervention results in important clinical benefit and either toxicity is uncommon or is strongly outweighed by the potential benefit (or vice versa).

A value of 2 indicates a lower degree of confidence that the desirable outcomes outweigh undesirable outcomes (or vice versa).

Strong recommendations are usually indicated by the phrase "the guideline panel recommends" and weak recommendations by the phrase "the guideline panel suggests."

The letter score within the grade indicates the quality of the underlying evidence:

A score of "A" suggests that the recommendation is supported by consistent evidence from randomized controlled trials (RCTs) or exceptionally strong observational studies.

A score of "B" suggests that the recommendation is supported by RCTs with important limitations or strong evidence from observational studies.

A score of "C" indicates evidence derived from RCTs with serious flaws, weaker observational studies, or indirect evidence.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Immune thrombocytopenia (ITP)

Guideline Category

Diagnosis

Evaluation

Management

Treatment

Clinical Specialty

Allergy and Immunology

Family Practice

Hematology

Infectious Diseases

Internal Medicine

Pediatrics

Surgery

Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

Guideline Objective(s)

• To summarize the literature describing the diagnosis and management of immune thrombocytopenia (ITP) focusing on changes since the

publication of the initial guideline in 1996

• To provide practicing clinicians with evidence-based guidance for the management of both primary and selected secondary forms of ITP

Target Population

Adults and children with primary and selected secondary forms of immune thrombocytopenia (ITP)

Note: The guidelines do not apply to neonatal ITP.

Interventions and Practices Considered

Diagnosis/Evaluation

- 1. Bone marrow examination (not necessary in evaluation)
- 2. Testing for antinuclear antibodies (not necessary in evaluation)
- 3. Helicobacter pylori testing for adults (not recommended routinely in children)
- 4. Hepatitis C virus testing for adults
- 5. Human immunodeficiency virus (HIV) testing for adults
- 6. Platelet count monitoring

Management/Treatment

- 1. Observation alone in cases of no or mild bleeding
- 2. Intravenous immunoglobulin (IVIg)
- 3. Corticosteroids (short or long course)
- 4. Anti-D immunoglobulin (anti-D) therapy (not advised in children with a hemoglobin concentration that is decreased due to bleeding, or with evidence of autoimmune hemolysis)
- 5. Rituximab
- 6. Splenectomy (laparoscopic or open)
- 7. High-dose dexamethasone
- 8. Measles-mumps-rubella vaccination in MMR-associated immune thrombocytopenia in children
- 9. Thrombopoietin receptor agonists
- 10. Antiviral therapy for patients with hepatitis C infection
- 11. Treatment of HIV infection with antiviral therapy
- 12. Eradication therapy in patients positive for H. pylori
- 13. Delivery methods based on obstetric indications for women in labor

Major Outcomes Considered

- Utility of diagnostic tests
- Incidence and severity of bleeding
- Platelet count
- Incidence of hemorrhage
- Efficacy of/response to treatments
- Rate of remission
- · Requirement for retreatment
- Development of persistent or chronic immune thrombocytopenia (ITP)
- Mortality
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The guideline panel used a rigorous systematic review process to ensure inclusion of all relevant articles and did not perform an exhaustive review of potential therapies for immune thrombocytopenia (ITP) (instead limiting the focus to those therapies with evidence).

The guideline panel searched the EMBASE and MEDLINE databases from 1996 to December 2009 for each of the clinical questions. Where literature searches revealed a methodologically rigorous systematic review or meta-analysis, they searched for subsequently published studies and updated the evidence for the published systematic review. If a systematic review was not available on a topic, they searched for relevant randomized controlled trials. The guideline panel did not include literature of lesser methodological quality in either of these situations. If they found no systematic reviews and no randomized controlled trials, they searched for rigorous cohort studies or case control studies with a preference for prospective cohort studies, retrospective cohort studies and case control studies, and finally case series. They confined inclusion of case studies to those enrolling more than 50 patients for adult series, and 25 patients for series of pediatric patients and patients with secondary ITP. Although the minimum number of patients selected was arbitrary, this was done to reduce the possibility of bias, which is more likely to be encountered in smaller studies. The lower threshold for pediatric and secondary ITP studies was chosen to balance the need to avoid bias against the need to have sufficient data to allow the guideline panel to make recommendations. This approach to literature is a modification of that used by the Scottish Intercollegiate Guidelines Network (SIGN) group.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

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A score of "C" indicates evidence derived from RCTs with serious flaws, weaker observational studies, or indirect evidence.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Evidence tables were constructed for each clinical question. If a table is not referenced in the text, the guideline panel was unable to find data to populate the table. In some cases more than one table was constructed for an individual question, for example, if more than one treatment modality is discussed.

The grades of recommendation for each of the clinical questions were proposed by a nominated principal author for that content area. Grades were then vetted in a series of teleconferences involving the authors of the guideline, at which time the evidence supporting the recommendation was reviewed in detail. Subsequently, an external panel was convened to ensure that all pertinent articles were identified and accurately assessed and determine whether all clinically relevant areas with evidence were addressed and evaluate whether the guideline was concise and organized.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The guideline panel began the guideline with the recommendations of the 1996 American Society of Hematology (ASH) guideline. Guideline development was separated into three parts: (1) development of a background consisting of recommendations on nomenclature, diagnosis, and response criteria (largely drawn from a recently published consensus document); (2) creation of focused clinical questions that form the basis for systematic literature review; and (3) establishment of evidence tables and the development of recommendations using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology.

Rating Scheme for the Strength of the Recommendations

The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system provides a score for a recommendation of 1A, 1B, 1C, 2A, 2B, or 2C. The numeric value indicates the strength of the recommendation.

A value of 1 indicates a high degree of confidence that the desirable outcomes of an intervention exceed the undesirable effects (or vice versa) in most patient populations. In general, a strong recommendation requires excellent-quality data from a variety of clinical situations. However, in some settings a strong recommendation may be derived from lesser-quality evidence if the intervention results in important clinical benefit and either toxicity is uncommon or is strongly outweighed by the potential benefit (or vice versa).

A value of 2 indicates a lower degree of confidence that the desirable outcomes outweigh undesirable outcomes (or vice versa).

Strong recommendations are usually indicated by the phrase "the guideline panel recommends" and weak recommendations by the phrase "the guideline panel suggests."

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Ultimately, the document was approved by the authors of the paper, The American Society of Hematology (ASH) Committee on Practice, ASH's Subcommittee on Quality of Care, and the ASH Executive Committee. The document then underwent a peer review process before submission for publication in *Blood*. Reviewers providing assessments of the paper before submission are found in an online appendix (available on the *Blood* Web site [see the "Availability of Companion Documents" field]).

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is graded and identified for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate management of immune thrombocytopenia

Potential Harms

Management of Immune Thrombocytopenia (ITP) in Children

Anti-D immunoglobulin (anti-D) is recommended only in patients who are Rhesus (Rh) positive, who have a negative direct antiglobulin test (DAT), and who have not undergone splenectomy. Additionally, clinicians are cautioned that the Food and Drug Administration (FDA) has provided a warning and specific monitoring requirements because of reports of fatal intravascular hemolysis reported with anti-D. As with all treatments, the risks of anti-D must be weighed against the benefits.

Management of ITP in Adults

- If anti-D is chosen as a therapy, care must be taken because of a risk of severe hemolysis that has been reported with some products.
- All of the treatments for patients who are unresponsive to or relapse after initial corticosteroid therapy have either proven long-term adverse events such as septicemia after splenectomy or other complications of potent immunosuppression (rituximab) or have been available for too short a time to comprehend fully long-term toxicities (eltrombopag and romiplostim). Septicemia in patients who have had splenectomy, for example, occurs with a relative risk of 1.4 (95% confidence interval [CI] 1.0-2.0) in the first year after splenectomy. The causative agent is Streptococcus pneumoniae in the majority of cases, and the case fatality rate approaches 50%.
- Eltrombopag and romiplostim have shown efficacy in randomized controlled trials in splenectomized or nonsplenectomized patients with persistent or chronic thrombocytopenia. When these agents are abruptly discontinued, thrombocytopenia typically recurs or transiently worsens, so clinicians and patients need to be vigilant for bleeding symptoms during this period. Adverse effects have generally been mild, although a recent study in patients with chronic liver disease was stopped because of an excess of portal venous thrombosis episodes in patients treated with eltrombopag. Thrombosis has not emerged as a major risk in other studies. The clinical significance of increased marrow reticulin fibrosis observed in 10 of 271 patients in the romiplostim trials and in seven of the long-term follow-up of eltrombopag patients (Promacta drug information [http://us.gsk.com/products/assets/us_promacta.pdf _______]) is unclear. Hepatotoxicity is important to monitor, because approximately 3% of eltrombopag-treated patients will have an increase of alanine aminotransferase (ALT) to at least 3 times the upper limit of normal compared with 0%-2% for controls, but in the majority this is nonprogressive or resolves.
- Rituximab is used in the management of adult patients with ITP who have failed one or more lines of therapy and who have undergone (in many cases) unsuccessful splenectomy. One study evaluated safety outcomes in 306 patients, of whom 10 (3.3%) had severe or life-threatening complications after rituximab treatment. Nine patients (2.9%) died. Thus 19 of 306 patients had grade 3, 4, or 5 toxicity as defined by the National Cancer Institute Common Terminology Criteria for Adverse Events. Progressive multifocal leukoencephalopathy has recently emerged as a complication of rituximab treatment; reports suggest this complication is rare in patients with ITP treated with rituximab.
- One review suggested that laparoscopic splenectomy had fewer complications than open splenectomy; however, this conclusion is limited by a lack of randomized studies.
- Although the risk of infection is the major cause of mortality after splenectomy, there have been several other complications that should be discussed with the patient when obtaining consent. These include bleeding, the need for transfusions, hernia formation, nerve palsies, intraabdominal adhesions leading to obstruction, and thrombosis.

Management of ITP during Pregnancy

Corticosteroids and IVIg are considered safe with regard to teratogenicity but may have maternal side effects including exacerbation of
gestational diabetes mellitus and postpartum psychiatric disorders. Cytotoxic agents such as cyclophosphamide and the vinca alkaloids are

- avoided during pregnancy because of an assumed risk of teratogenicity, although data on the magnitude of the risk are limited.
- Splenectomy may increase the risk of preterm labor during the first trimester and can be technically difficult because of the size of the uterus
 in the third trimester, but data regarding the magnitude of risk are lacking, as are data regarding the risks with laparoscopic splenectomy.
 The guideline panel identified no evidence for specific platelet thresholds at which pregnant patients with ITP should be treated; as with other
 patients, clinicians should consider the risks and benefits of any proposed treatment plans with a particular focus on major maternal
 complications including both those because of the ITP and those because of the drugs used to increase the platelet counts.

Treatment of Specific Forms of Secondary ITP

- Hepatitis C virus (HCV)-associated secondary ITP: Whereas antiviral treatment can result in improvement in the platelet count, thrombocytopenia is a recognized side effect of interferon therapy.
- Corticosteroids may increase the platelet count, but may also increase the HCV viral load.
- Human immunodeficiency virus (HIV)-associated secondary ITP: Splenectomy is an effective option for patients failing to respond to corticosteroids or intravenous immunoglobulin (IVIg), but overall risks of the procedure are unclear in this patient population.

Contraindications

Contraindications

Manufacturers recommend that the presence of thrombocytopenia with a platelet count $<75 \times 10^9$ /L is a relative contraindication to interferon therapy.

Qualifying Statements

Qualifying Statements

- This guideline discusses both licensed and unlicensed drugs for the treatment of immune thrombocytopenia (ITP). Before administering drugs, physicians should be aware of the method of administration and possible side effects, ensure that there is a safe environment for the administration of the drugs, and ensure that preadministration tests are given for those drugs that require them (e.g., hepatitis serology before rituximab). Patients and caregivers should be adequately consented.
- In all cases, a recommendation should not replace best physician judgment and a patient's stated preference; recommendations are guides that cannot be applied uniformly to all patients.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Quick Reference Guides/Physician Guides

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Neunert C, Lim W, Crowther M, Cohen A, Solberg L Jr, Crowther MA, American Society of Hematology. The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. Blood. 2011 Apr 21;117(16):4190-207. [162 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Apr 21

Guideline Developer(s)

American Society of Hematology - Medical Specialty Society

Source(s) of Funding

American Society of Hematology

Guideline Committee

Guideline Panel

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

The guideline panel consisted of authors who had no significant conflicts of interest as defined by the American Society of Hematology (ASH)

Conflict of Interest policy (http://www.hematology.org/About-ASH/1779.aspx, accessed June 8, 2010). Thus, none of
the authors of this guideline had received honorarium or other forms of direct or indirect financial support from pharmaceutical companies that
manufacture products discussed in this guideline. Furthermore, none of the authors had received direct research support from companies manufacturing products discussed in this report in the 24 months before their coming on the panel.
Conflict-of-interest disclosure: The authors declare no competing financial interests.
Guideline Status
This is the current release of the guideline.
Guideline Availability
Electronic copies: Available in Portable Document Format on the <i>Blood</i> Web site
Information about ordering reprints may be found online at: http://bloodjournal.hematologylibrary.org/site/misc/rights.xhtml#reprints
Availability of Companion Documents
The following are available:
• The American Society of Hematology 2011 evidence-based practice guideline for immune thrombocytopenia. Supplemental materials. Available in Portable Document Format (PDF) on the <i>Blood</i> Web site.
 2011 clinical practice guideline on the evaluation and management of immune thrombocytopenia (ITP). Presented by the American Society of Hematology, adapted from The American Society of Hematology 2011 evidence-based practice guideline for immune
thrombocytopenia. Quick Reference Guide. 2011. 8 p. Available in Portable Document Format (PDF) from the American Society of
Hematology Web site
Patient Resources
None available
NGC Status

This NGC summary was completed by ECRI Institute on July 30, 2012. This summary was updated by ECRI Institute on November 21, 2013 following the U.S. Food and Drug Administration advisory on Arzerra (ofatumumab) and Rituxan (rituximab).

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